Complete Summary

GUIDELINE TITLE

Guidelines for using the QuantiFERON®-TB test for diagnosing latent mycobacterium tuberculosis infection.

BIBLIOGRAPHIC SOURCE(S)

Mazurek GH, Villarino ME. Guidelines for using the QuantiFERON-TB test for diagnosing latent Mycobacterium tuberculosis infection. Centers for Disease Control and Prevention. MMWR Recomm Rep 2003 Jan 31;52(RR-2):15-8. [6 references] PubMed

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Latent Mycobacterium tuberculosis infection

GUIDELINE CATEGORY

Diagnosis
Evaluation

CLINICAL SPECIALTY

Family Practice
Infectious Diseases
Internal Medicine
Pathology
Preventive Medicine
Pulmonary Medicine

INTENDED USERS

Clinical Laboratory Personnel
Health Care Providers
Public Health Departments

GUIDELINE OBJECTIVE(S)

To assist public health officials, health-care providers, and laboratorians who are responsible for tuberculosis control activities in the United States in their efforts to incorporate QuantiFERON-TB® testing for detecting and treating latent Mycobacterium tuberculosis infection

TARGET POPULATION

- Persons at increased risk for latent Mycobacterium tuberculosis infection (e.g., recent immigrants, injection-drug users, and residents and employees of prisons and jails)
- Persons at low risk for latent Mycobacterium tuberculosis infection but whose future activity might place them at increased risk (e.g., health-care workers and military personnel)
- Persons who are not considered to have an increased probability of Mycobacterium tuberculosis infection but who require testing for other reasons

INTERVENTIONS AND PRACTICES CONSIDERED

QuantiFERON-TB® test for diagnosis of latent Mycobacterium tuberculosis infection

MAJOR OUTCOMES CONSIDERED

Detection of latent Mycobacterium tuberculosis infection

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The highest priority of targeted tuberculin testing programs remains one that identifies persons at increased risk for tuberculosis (TB) who will benefit from treatment for latent tuberculosis infection (LTBI). Following that principle, targeted tuberculin testing should be conducted among groups at risk for recent infection with Mycobacterium tuberculosis and those who, regardless of duration of infection, are at increased risk for progression to active TB.

The role of QuantiFERON-TB® test (QFT) in targeted testing has not yet been defined, but QFT can be considered for LTBI screening as follows:

- initial and serial testing of persons with an increased risk for LTBI (e.g., recent immigrants, injection-drug users, and residents and employees of prisons and jails)
- initial and serial testing of persons who are, by history, at low risk for LTBI but whose future activity might place them at increased risk for exposure, and others eligible for LTBI surveillance programs (e.g., health-care workers and military personnel)
- testing of persons for whom LTBI screening is performed but who are not considered to have an increased probability of infection (e.g., entrance requirements for certain schools and workplaces)

Before QFT testing is contemplated, arrangements should be made with a qualified laboratory. Those arrangements should include quality assurance and collection and transport of blood within the required 12 hours.

Confirmation of QFT results with tuberculin skin testing (TST) is possible because performance of QFT does not affect subsequent QFT or TST results. The probability of LTBI is greatest when both the QFT and TST are positive. Considerations for confirmation are as follows:

- When the probability of LTBI is low, confirmation of a positive QFT result with TST is recommended before initiation of LTBI treatment. LTBI therapy is not recommended for persons at low risk who are QFT-negative or who are QFT-positive but TST-negative.
- TST can also be used to confirm a positive QFT for persons at increased risk for LTBI. However, the need for LTBI treatment when QFT is positive and the subsequent TST is negative should be based on clinical judgment and perceived risk.
- Negative QFT results do not require confirmation, but results can be confirmed with either a repeat QFT or TST if the accuracy of the initial test is in question.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not specifically stated.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Compared with tuberculin skin testing (TST), QuantiFERON-TB® test (QFT) results are less subject to reader bias and error.

- Targeted tuberculin testing programs may identify persons at increased risk for tuberculosis who will benefit from treatments for latent tuberculosis infection (LTBI).

POTENTIAL HARMS

False-negative QuantiFERON-TB® test (QFT) results

CONTRAINDICATIONS

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Because of insufficient data on which to base recommendations, QuantiFERON-TB® testing (QFT) is not recommended for:

- evaluation of persons with suspected tuberculosis. Active tuberculosis is associated with suppressed interferon (IFN-gamma) responses, and in prior studies, fewer persons with active tuberculosis (TB) had positive QFT results than tuberculin skin testing (TST) results. The degree of suppression appears to be related to the severity of disease and the duration of therapy. Studies are under way that compare the sensitivity of QFT and TST among persons with untreated active TB.
- assessment of contacts of persons with infectious tuberculosis, because rates of conversion of QFT and TST after a known exposure to Mycobacterium tuberculosis have not been compared, and concordance of QFT and TST after exposure and with serial latent tuberculosis infection (LTBI) screening have not been studied.
- screening of children aged <17 years, pregnant women, or for persons with clinical conditions that increase the risk for progression of LTBI to active TB (e.g., human immunodeficiency virus infection). Further studies are needed to define the appropriate use of QFT among these persons.
- detection of LTBI after suspected exposure (i.e., contact investigation after a resident or employee is diagnosed with active TB or a laboratory spill of M. tuberculosis) of persons participating in longitudinal LTBI surveillance programs. The approach of using QFT for initial screening, followed by QFT and TST 3 months after the end of the suspected exposure, has not been evaluated.
- confirmation of TST results because injection of purified protein derivative (PPD) for TST might affect subsequent QFT results. Although QFT is not recommended for confirmation of TST results, QFT can be used for surveillance <12 months after a negative TST, if the initial QFT is negative.
- diagnosis of Mycobacterium avium complex disease.

QUALIFYING STATEMENTS

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Use of trade names and commercial sources is for identification only and does not imply endorsement by the United States Department of Health and Human Services.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Mazurek GH, Villarino ME. Guidelines for using the QuantiFERON-TB test for diagnosing latent Mycobacterium tuberculosis infection. Centers for Disease Control and Prevention. MMWR Recomm Rep 2003 Jan 31;52(RR-2):15-8. [6 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2003 Jan 31

GUIDELINE DEVELOPER(S)

Centers for Disease Control and Prevention - Federal Government Agency [U.S.]

SOURCE(S) OF FUNDING

United States Government

GUIDELINE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Report Prepared by: Gerald H. Mazurek, M.D. and Margarita E. Villarino, M.D. (Division of Tuberculosis Elimination, National Center for HIV, STD, and TB Prevention)

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Centers for Disease Control and Prevention (CDC) Web site:

- HTML Format
- Portable Document Format (PDF)

Print copies: Available from the Centers for Disease Control and Prevention, MMWR, Atlanta, GA 30333. Additional copies can be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402-9325; (202) 783-3238.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

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